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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,693	02/08/2000	Insu Lee	00120/P-4858	1622

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EXAMINER
WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
1617	28

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/499,693	Applicant(s) LEE ET AL.	
	Examiner Lauren Q Wells	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 26-45 are pending. The Amendment filed 2/18/03, Paper No. 25, amended claims 26, 30-34, 38 and 42.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/9/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "and alpha-linolenic fatty" in claim 26 (line 2) is vague and indefinite, as it is confusing. Fatty what? Did Applicant omit the term "acid" from this phrase or is Applicant describing something else?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26, 34, 38, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leach (5,612,074).

The instant invention is directed toward an unsaturated fatty acid composition consisting essentially of linoleic fatty acid and alpha-linolenic fatty acid in a ratio of 0.05-7.5, and wherein said composition contains flaxseed oil.

Leach teaches a nutrient fortified food bar. Taught is an uncooked food bar consisting essentially of dry ingredients combined with a mixture of liquid ingredients, wherein the liquid ingredients include at least one vegetable oil containing polyunsaturated linoleic acid and at least on vegetable oil containing alpha-linolenic acid, wherein the linoleic to linolenic ratio is 3:1 in the food bar. Flax seed is recited as an oil for use in the composition. The reference lacks an exemplification of flax seed in the food bar. See Col. 9, line 20-Col. 16, line 38.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify flax seed oil as the vegetable oil in the food bar of Leach because flax seed oil is taught as a preferred oil in the instant invention and because of the expectation of achieving a food bar that maintains a ratio of linoleic to linolenic fatty acid that is in the ratio of 3:1.

The Examiner respectfully points out that for the purposes of searching for an applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of

showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

Claims 27, 31, 35, 39 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leach, as applied to claims 26, 34, 38, 42 above, in view of Erasmus et al. (5,656,312) and Hunter et al. (4,863,753).

Leach is applied as discussed above. The reference lacks rapeseed and perilla oil.

Erasmus et al. teach a dietary food supplement. Perilla and flax seed oils are disclosed as combinable oils. See Col. 11, lines 24-Col. 14, line 43.

Hunter et al. teach composition comprising reduced calorie peanut butter. Perilla oil and rapeseed oil are both disclosed as oils that can be used as fatty acids in the composition. Rapeseed oil is disclosed a stabilizer for the oil phase of the composition. See Col. 6, lines 3-34.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the perilla seed oil of Eramus et al. to the composition of Leach because a) Leach and Erasmus are both directed to food supplements; b) Erasmus teaches that perilla seed oil and flax seed oil can be in composition together in a food supplement; and c) Leach teaches that the liquid phase of his composition can comprise one or more seeds containing linolenic acid, and Hunter teaches perilla oil as a source of linolenic acid; thus, one of skill in the art would have been motivated to add the perilla oil and rapeseed oil to the composition of Leach because of the expectation of achieving enhanced nutritional benefits.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the rapeseed oil of Hunter et al. to the composition of the combined references because Hunter teaches the combination of rapeseed oil and perilla oil in composition together in

a food supplement, and teaches rapeseed oil as providing stability to the oil phase of compositions; thus, one of skill in the art would have been motivated to add the rapeseed oil of Hunter to the composition of the combined references because of the expectation of increasing the stability of the composition.

Claims 28, 30, 32, 36, 40, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leach as applied to claims 26, 34, 38, 42 above, and further in view of Igarashi (6,159,507).

Leach is applied as discussed above. The reference lacks preferred ratios and capsule forms of the composition.

Igarashi teaches food compositions containing an omega-6/omega-3 unsaturated fatty acid balance modifier. Igarashi teaches that food compositions comprising a ratio of omega-3 fatty acids to omega-66 fatty acids is 1:1 to 1:5 are known. Furthermore the reference teaches that the normal balance to be inherently maintained in the body of omega-6 to omega-3 fatty acids is 1:5 and preferably 2 to 4. Capsule forms of the composition are disclosed. See Col. 5, line 64-Col. 6, line 40; Col. 7, lines 1-8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Igarashi into the invention of the combined references and obtain a ratio of linoleic to linolenic acid of 0.05-2 because a) the Leach and Igarashi are both directed to food products, and Igarashi teaches that ratios of 1:1 to 1:5 are known to be used in food compositions and he furthermore teaches that the body prefers a ratio of 1:5 for optimum health. Thus, one of skill in the art would be motivated to incorporate the ratios of omega-6 to omega-3 fatty acids of Igarashi into the composition of Leach because of the expectation of

producing a food bar that maintains the proper physiological balance of omega-6 to omega-3 fatty acids in the body, and hence health.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the food bar of Leach in the form of a capsule, as taught by Igarashi, because of the expectation of achieving an easily administrable nutritional supplement.

Claims 29, 33, 37, 41 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leach in view of Eramus et al. and Hunter et al., as applied to claims 26, 27, 31, 34, 35, 38, 39, 42, and 43 above, in view of Igarashi (6,159,507).

Leach, Eramus et al, and Hunter et al. are applied as discussed above. The references lack preferred ratios.

Igarashi teaches food compositions containing an omega-6/omega-3 unsaturated fatty acid balance modifier. Igarashi teaches that food compositions comprising a ratio of omega-3 fatty acids to omega-66 fatty acids is 1:1 to 1:5 are known. Furthermore the reference teaches that the normal balance to be inherently maintained in the body of omega-6 to omega-3 fatty acids is 1:5 and preferably 2 to 4. Capsule forms of the composition are disclosed. See Col. 5, line 64-Col. 6, line 40; Col. 7, lines 1-8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Igarashi into the invention of the combined references and obtain a ratio of linoleic to linolenic acid of 0.05-2 because a) the combined references and Igarashi are both directed to food products, and Igarashi teaches that ratios of 1:1 to 1:5 are known to be used in food compositions and he furthermore teaches that the body prefers a ratio of 1:5 for optimum health. Thus, one of skill in the art would be motivated to incorporate the

ratios of omega-6 to omega-3 fatty acids of Igarashi into the composition of Leach because of the expectation of producing a food bar that maintains the proper physiological balance of omega-6 to omega-3 fatty acids in the body, and hence health.

Response to Arguments

Applicant argues, "Leach teaches that the linoleic/linolenic ratio of the oil seeds in the dry ingredients and the vegetable oil in the liquid ingredients should be in a 3:1 ratio. This is in contradistinction to the teaching of an end product having a linoleic/linolenic ratio of 3:1, since it is clear that the resulting food bar in Leach will not have a linoleic/linolenic ratio of 3:1". This argument is not persuasive. The Examiner respectfully directs Applicant to the abstract of Leach which specifically states, "The food bar contains about 35% by weight of complex carbohydrates, about 17% by weight of simple carbohydrates, with polyunsaturated linoleic acid present in a ratio of about 3:1 by weight to superunsaturated alphaplinolenic acid".

Furthermore, regarding the ratios, the Examiner respectfully points out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding the phrase "consisting essentially of", Applicant states "Applicants submit that the food bar taught by Leach contains numerous ingredients that materially effect the ratio of linoleic/linolenic fatty acid". This argument is not persuasive. Again, the Examiner respectfully points out that if an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics ***of applicant's invention***. See MPEP 2111.03. The Examiner respectfully suggests that Applicant

provide a declaration that shows that introduction of additional steps or components would materially change the characteristics of applicant's invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
May 7, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

5/14/03